

## **EXHIBIT 4**

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**FILED**  
**SAN MATEO COUNTY**

NOV 10 2016

Clerk of the Superior Court

By                       
DEPUTY CLERK

**SUPERIOR COURT OF THE STATE OF CALIFORNIA**

**COUNTY OF SAN MATEO**

NARBEH NATHAN, Individually and on Behalf  
of All Others Similarly Situated,

Plaintiff,

vs.

REWALK ROBOTICS LTD., LARRY  
JASINSKI, AMI KRAFT, AMIT GOFFER,  
JEFF DYKAN, HADAR RON, ASAF SHINA,  
WAYNE B. WEISMAN, YASUSHI ICHIKI,  
ARYEH DAN, GLENN MUIR, BARCLAYS  
CAPITAL INC., JEFFERIES LLC, and  
CANACCORD GENUITY INC.,

Defendants.

Case No.: \_\_\_\_\_

**16CIV02345**

**CLASS ACTION COMPLAINT  
FOR VIOLATIONS OF  
SECURITIES ACT OF 1933**

**DEMAND FOR JURY TRIAL**

16 - CIV - 02345  
CMP  
Complaint Filed  
252463



1 Plaintiff alleges the following based upon Plaintiff's own acts, and upon information and  
2 belief as to all other matters based upon the investigation of Plaintiff's counsel, which included,  
3 among other things, a review of United States Securities and Exchange Commission ("SEC") filings  
4 by ReWalk Robotics LTD. ("ReWalk" or the "Company"), securities analysts' reports and  
5 advisories about the Company, press releases and other public statements issued by the Company,  
6 and media reports about the Company. Plaintiff believes that substantial additional evidentiary  
7 support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

#### 8 NATURE OF THE ACTION

9 1. This is a securities class action on behalf of all persons who purchased ReWalk  
10 common stock in and/or traceable to ReWalk's September 12, 2014, initial stock offering (the  
11 "IPO"), seeking to pursue remedies under the Securities Act of 1933 (the "1933 Act").

12 2. ReWalk is a medical device company that specializes in the design, development and  
13 commercialization of wearable, robotic exoskeletons for use by individuals with spinal cord injury.  
14 At the time of its IPO, the Company offered two products: ReWalk Rehabilitation and ReWalk  
15 Personal. ReWalk Rehabilitation, introduced internationally in 2011, are exoskeletons designed for  
16 therapeutic use by individuals in clinical rehabilitation facilities and can prepare those individuals for  
17 the future use of ReWalk Personal. ReWalk Personal, introduced in Europe in 2012 and approved for  
18 sale in the United States in June 2014, are "the first exoskeleton[s] cleared by the FDA for personal  
19 use" and are meant to be used by individuals daily.

20 3. On July 10, 2014, ReWalk filed with the SEC a registration statement on Form F-1  
21 (the "Registration Statement"). The Registration Statement, after several amendments, became  
22 effective on September 11, 2014. On September 12, 2014, ReWalk and the Underwriter Defendants  
23 priced the IPO at \$12 per share. On September 15, 2014, the Company filed the final prospectus for  
24 the IPO (the "Prospectus") with the SEC (the Prospectus and Registration Statement are collectively  
25 referred to herein as the "Registration Statement").

26 4. On September 17, 2014, the Company announced the closing of its offering of  
27 3,450,000 ordinary shares to the public (including 450,000 shares pursuant to the full exercise of the  
28

underwriter's option to purchase additional shares). In total, the Company raised roughly \$41.4 million in the IPO, which translated into more than \$36 million in net proceeds.

5. The Registration Statement described the Company's exoskeleton products and outlined its various development plans and commercialization efforts. The Company's Registration Statement, however, was negligently prepared, contained untrue statements of material facts, and omitted facts necessary to make other statements not misleading. Specifically, the Registration Statement failed to disclose that the ReWalk was unprepared and/or unable to comply with applicable "special controls" requirements or to provide the FDA with a postmarket surveillance study required to maintain ongoing sales of its exoskeletons. Investors who purchased the Company's stock pursuant to its IPO have been damaged as a result

#### **JURISDICTION AND VENUE**

6. The claims alleged herein arise under §§11, 12(a)(2), and 15 of the 1933 Act, 15 U.S.C. §§77k, 77l(a)(2) and 77o. Jurisdiction is conferred by §22 of the 1933 Act and venue is proper pursuant to §22 of the 1933 Act. Section 22 of the 1933 Act explicitly states that "[e]xcept as provided in section 16(c), no case arising under this subchapter and brought in any State court of competent jurisdiction shall be removed to any court in the United States." Section 16(c) refers to "covered class actions," which are defined as lawsuits brought as class actions or brought on behalf of more than 50 persons asserting claims under state or common law. This is an action asserting federal law claims. Thus, it does not fall within the definition of a "covered class action" under §16(b)-(c) and is not removable to federal court under the Securities Litigation Uniform Standards Act of 1998.

7. The violations of law complained of herein occurred in this County, including the dissemination of materially false and misleading statements complained of herein into this County. ReWalk is located and conducts business in this County.

#### **PARTIES**

8. Plaintiff Narbeh Nathan acquired the common stock of ReWalk pursuant or traceable to the IPO and has been damaged thereby.

1           9. Defendant ReWalk is an Israeli medical device company that was founded in 2001  
2 and has 10 Training Centers in California. The Company's shares trade on the NASDAQ Global  
3 Market under the symbol "RWLK." The Company went public on or about September 12, 2014.

4           10. Larry Jasinski ("Jasinski") signed the Registration Statement as the Company's Chief  
5 Executive Officer (the "CEO") and a member of the Board of Directors (the "Board"). Jasinski has  
6 served as a Company director and its CEO since 2012.

7           11. Ami Kraft ("Kraft") signed the Registration Statement as the Company's Chief  
8 Financial Officer. Kraft has served as Senior Vice President and General Manager for ReWalk since  
9 2015.

10           12. Amit Goffer ("Goffer") signed the Registration Statement as the Company's  
11 President, Chief Technical Officer ("CTO") and a member of the Board. Goffer is the Company's  
12 founder and previously served as its CEO and CTO. Defendant Goffer resigned from the Company  
13 effective November 18, 2015.

14           13. Jeff Dykan ("Dykan") signed the Registration Statement as Chairman of the Board.  
15 Dykan has served as Company director since 2006 and has been the Chairman of its Board since  
16 2009.

17           14. Hadar Ron ("Ron") was a director of ReWalk until April 2015. Defendant Ron  
18 signed the false and misleading Registration Statement.

19           15. Asaf Shinar ("Shina") was a director of ReWalk until February 2015. Defendant  
20 Shinar signed the false and misleading Registration Statement.

21           16. Wayne B. Weisman ("Weisman") is, and at all relevant times was, a director of  
22 ReWalk. Defendant Weisman signed the false and misleading Registration Statement.

23           17. Yasushi Ichiki ("Ichiki") is, and at all relevant times was, a director of ReWalk.  
24 Defendant Ichiki signed the false and misleading Registration Statement.

25           18. Aryeh Dan ("Dan") is, and at all relevant times was, a director of ReWalk. Defendant  
26 Dan signed the false and misleading Registration Statement...

27           19. Glenn Muir ("Muir") is, and at all relevant times was, a director of ReWalk.  
28 Defendant Muir signed the false and misleading Registration Statement..

20. Defendant Barclays Capital Inc. (“Barclays”) is a financial services company with offices in Los Angeles (10250 Constellation Blvd., 24th Floor, Los Angeles, CA 90067), San Francisco (555 California St., 7th Floor, San Francisco, CA 94104) and Menlo Park (155 Linfield Drive, Menlo Park, CA 94025), which is in San Mateo.

21. Defendant Jefferies LLC (“Jefferies”) is a financial services company with offices in Los Angeles (11100 Santa Monica Blvd., Los Angeles, CA 90025), San Francisco (101 California St., 31st Floor, San Francisco, CA 94111) and Foster City (950 Tower Lane, 21st Floor, Foster City, Ca 94404), which is in San Mateo County.

22. Defendant Canaccord Genuity Inc. (“Canaccord”) is a financial services company located at 101 Montgomery Street, Suite 2000, San Francisco, CA 94104.

23. Defendants Jasinski, Kraft, Goffer, Dykan, Ron, Shina, Weisman, Ichiki, Dan and Muir are referred to herein as the “Individual Defendants.”

24. Defendants Barclays, Jefferies and Canaccord served as underwriters of the IPO, helping to draft and disseminate the offering documents and to sell the Company’s IPO stock to the investing public, including Plaintiff. These defendants are referred to herein as the “Underwriter Defendants.” The Underwriter Defendants’ failure to conduct adequate due diligence investigations was a substantial factor leading to the harm complained of herein. Pursuant to the Securities Act of 1933, the Underwriter Defendants are liable for the materially false and misleading statements in the Registration Statement as follows:

a. The Underwriter Defendants are investment banking houses which specialize in, among other things, underwriting public offerings of securities.

b. Barclays and Jefferies acted as representatives of the underwriters as the joint book-running managers of the offering. By the close of the IPO on September 17, 2014, the Company announced the sale of 3,450,000 shares at \$12 per share, generating gross proceeds of \$41.4 million or net proceeds of \$36.3 million (after deducting expenses, underwriting discounts and commissions).

c. The Underwriter Defendants underwrote the IPO and shared roughly \$2.7 million in fees collectively.

d. The Underwriter Defendants demanded and obtained an agreement from ReWalk that ReWalk would indemnify and hold the Underwriter Defendants harmless from any liability under the federal securities laws.

e. Representatives of the Underwriter Defendants assisted ReWalk and the Individual Defendants in planning the IPO, and had continual access to confidential corporate information concerning ReWalk's operations and financial prospects.

f. The Underwriter Defendants caused the Registration Statement to be filed with the SEC and declared effective.

#### **REWALK ROBOTICS' BACKGROUND**

25. ReWalk was founded in 2001 by Defendant Goffer, who served as the Company's CEO and CTO until 2012. ReWalk was formerly called Argo Medical Technologies, Inc. ("Argo"). In August 2015, Defendant Goffer announced his resignation from the Company, effective November 18, 2015. Defendant Goffer thereafter devoted substantially more time toward working at a competitor of ReWalk – a company he founded in 2013 called UPnRIDE Robotics Ltd. ("UPnRIDE") (fka RehaMed Technologies Ltd.).

26. In its Registration Statement, ReWalk described itself as "developing and commercializing exoskeletons" that would give users "the ability to stand and walk once again" and asserted that:

ReWalk is a breakthrough product that can fundamentally change the health and life experiences of users. ReWalk is currently the only commercialized exoskeleton using a tilt sensor to restore self-initiated walking.

Registration Statement at 1.

27. The Company obtained FDA approval to market ReWalk Personal in June 2014 and turned its attention to the sale of its products, which, as stated in the Registration Statement, would be led by ReWalk Personal and financed by a combination of self- and third-party payors, such as insurers. According to the Registration Statement:

Our commercialization strategy is to penetrate rehabilitation centers, hospitals and similar facilities that treat patients with spinal cord injuries to become an integral part of their rehabilitation programs and to develop a broad based training network with these facilities to prepare users for home and community use.

1 We expect to generate revenues from a combination of self-payors and third-party  
2 payors. While no uniform policy of coverage and reimbursement by third-party  
3 payors currently exists for electronic exoskeleton technologies such as ReWalk in the  
4 United States or elsewhere, we plan to pursue various paths of reimbursement and  
support fundraising efforts by institutions and clinics.

5 28. The June 2014 FDA approval to sell ReWalk Personal was accompanied by a  
6 requirement that the Company conduct postmarket surveillance studies to determine the product's  
7 safety and effectiveness to users after it was released to the public. As stated by the FDA:

8 Postmarket surveillance is a collection of processes and activities the FDA uses to  
9 monitor the safety and effectiveness of medical devices once they are on the market.  
10 These activities are designed to generate information to quickly identify poorly  
11 performing devices and other safety problems, accurately characterize real-world  
device performance and clinical outcomes and facilitate the development of new  
devices, or new uses for existing devices.

12 See U.S. Food & Drug Administration, Device Postmarket Surveillance (available at  
13 <http://www.fda.gov/MedicalDevices/Safety/CDRHPostmarketSurveillance/default.htm>).

14 29. The FDA's postmarket surveillance requirements are outlined in federal regulation 24  
15 CFR 822.10.

16 30. In 2002, the FDA discussed postmarket surveillance ("PS") and reiterated its support  
17 of the surveillance requirement by stating that:

18 Several comments expressed concern that the proposed rule would impose  
19 substantial, unnecessary burdens on device manufacturers, and proposed a number of  
20 changes that would reduce the burden. Individual changes are addressed in the  
21 appropriate regulation sections. One comment stated that existing systems, such as  
medical device reports (MDRs), are adequate to provide safety and effectiveness  
information.

22 We do not agree. If Congress thought that existing mechanisms were sufficient, it  
23 would not have provided for PS [postmarket surveillance]. We recognize the  
24 potential for PS to be burdensome, but do not agree that any burden imposed by PS  
25 would be unnecessary. We intend to impose PS only when necessary to address a  
26 postmarket public health question. We also intend to work with the affected  
manufacturer(s) to identify the least burdensome approach that will adequately  
address the surveillance question.

27 67 FR 38878, June 6, 2002, at 3.



31. A manufacturer's failure to comply with postmarket surveillance requirements may result in the FDA taking further action, such as seizure, injunction and/or civil penalties. Such FDA action would prevent the sale or marketing of a medical product manufacturer's products.

32. Lastly, upon granting approval for ReWalk Personal in June 2014, the FDA sent a letter to ReWalk outlining certain specific health risks associated with its product (such as "instability," "skin abrasions," "changes in blood pressure," etc.) and asked for ReWalk to conduct additional "clinical testing." The FDA further detailed a long list of "special controls" that needed to be undertaken for ReWalk Personal to ensure its safety and effectiveness. Those "special controls" include the following:

- Elements of the device materials that may contact the patient must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electronic compatibility/interference (EMC/EMI), electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.
- Appropriate software verification, validation, and hazard analysis must be performed.
- Design characteristics must ensure geometry and materials composition are consistent with intended use.
- Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:
  - Mechanical bench testing (including durability testing) to demonstrate that the device will withstand forces, conditions and environments encountered during use.
  - Simulated use testing (i.e. cyclic loading testing) to demonstrate performance of device commands and safeguard under worst case conditions and after durability testing.
  - Verification and validation of manual override controls are necessary, if present.
  - The accuracy of device features and safeguards.
  - Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor performance.
- Clinical testing must demonstrate safe and effective use and capture any adverse events observed during clinical use when used under the proposed conditions of use, which must include considerations for:
  - Level of supervision necessary
  - Environment of use (e.g., indoors and/or outdoors) including obstacles and terrain representative of the intended use environment

- 1       ● A training program must be included with sufficient educational elements so that  
2       upon completion of training program, the clinician, user and companion can:
  - 3           ○ Identify the safe environments for device use
  - 4           ○ Use all safety features of device
  - 5           ○ Operate the device in simulated or actual use environments representative  
6       of indicated environments and use
- 7       ● Labeling for the Physician and User must include the following:
  - 8           ○ appropriate instructions, warning, cautions, limitations, and information  
9       related to the necessary safeguards of the device, including warning against activities  
10      and environments that may put the user at greater risk.
  - 11          ○ specific instructions and the clinical training needed for the safe use of the  
12      device, which includes:
    - 13           • instructions on assembling the device in all available  
14          configurations,
    - 15           • instructions on fitting the patient,
    - 16           • instructions and explanations of all available programs and how to  
17          program the device,
    - 18           • instructions and explanation of all controls, input, and outputs,
    - 19           • instructions on all available modes or states of the device,
    - 20           • instructions on all safety features of the device, and
    - 21           • instructions for properly maintaining the device.
  - 22          ○ information on the patient population for which the device has been  
23      demonstrated to have a reasonable assurance of safety and effectiveness.
  - 24          ○ pertinent non-clinical testing information (e.g., EMC, battery longevity)
  - 25          ○ a detailed summary of the clinical testing including:
- 26       ● Adverse events encountered under use conditions.
- 27       ● Summary of study outcomes and endpoints.
- 28       ● Information pertinent to use of the device including the conditions under which  
the device was studied [e.g., level of supervision or assistance, and environment of  
use (e.g., indoors and/or outdoors) including obstacles and terrain].

Letter, dated June 26, 2014, from Jonette Foy of the FDA to John Hamilton, ReWalk's Vice  
President of Regulatory, Clinical Reimbursement and Service.

### **DEFENDANTS' FALSE AND DEFECTIVE REGISTRATION STATEMENT AND PROSPECTUS**

33.     The Registration Statement contained untrue statements of material facts and omitted  
to state facts necessary to make certain statements therein not misleading.

34.     In its Registration Statement, the Company discussed the current U.S. regulatory  
market for medical devices and the FDA classification system applicable to its exoskeleton product.

1 In a section entitled “Premarket Regulation,” the Registration Statement included the following  
2 description:

3 Unless an exemption applies, each medical device commercially distributed in the  
4 United States requires either a substantial equivalence determination under a 510(k)  
5 premarket notification submission, or an approval of a premarket approval  
6 application (PMA). Under the FFDCA [Federal Food, Drug, and Cosmetic Act],  
7 medical devices are classified into one of three classes—Class I, Class II or Class  
8 III—depending on the degree of risk associated with each medical device and the  
9 extent of control needed to provide reasonable assurance of safety and effectiveness.  
10 Classification of a device is important because the class to which a device is assigned  
11 determines, among other things, the necessity and type of FDA review required prior  
12 to marketing the device. Class I devices are those for which reasonable assurance of  
13 safety and effectiveness can be assured by adherence to general controls that include  
14 compliance with the applicable portions of the FDA’s Quality System Regulation, or  
15 QSR, facility registration and product listing, reporting of adverse medical events,  
16 and appropriate, truthful and non-misleading labeling, advertising, and promotional  
17 materials. Class I also includes devices for which there is insufficient information to  
18 determine that general controls are sufficient to provide reasonable assurance of the  
19 safety and effectiveness of the device or to establish special controls to provide such  
20 assurance, but that are not life-supporting or life-sustaining or for a use which is of  
21 substantial importance in preventing impairment of human health, and that do not  
22 present a potential unreasonable risk of illness or injury.

23 Class II devices are those for which general controls alone are insufficient to provide  
24 reasonable assurance of safety and effectiveness and there is sufficient information to  
25 establish “special controls.” These special controls can include performance  
26 standards, postmarket surveillance, patient registries and FDA guidance documents.  
27 While most Class I devices are exempt from the 510(k) premarket notification  
28 requirement, only about 60 types of Class II devices are exempt from premarket  
notification. As a result, manufacturers of most Class II devices are required to  
submit to the FDA premarket notifications under Section 510(k) of the FFDCA  
requesting classification of their devices in order to market or commercially  
distribute those devices. To obtain a 510(k), a substantial equivalence determination  
for their devices, manufacturers must submit to the FDA premarket notifications  
demonstrating that the proposed device is “substantially equivalent” to a predicate  
device already on the market. A predicate device is a legally marketed device that is  
not subject to premarket approval, *i.e.*, a device that was legally marketed prior to  
May 28, 1976 (pre-amendments device) and for which a PMA is not required, a  
device that has been reclassified from Class III to Class II or I, or a device that was  
found substantially equivalent through the 510(k) process. If the FDA agrees that the  
device is substantially equivalent to a predicate device currently on the market, it will  
grant 510(k) clearance to commercially market the device. If the device is not  
“substantially equivalent” to a previously cleared device, the device is automatically  
a Class III device. The device sponsor must then fulfill more rigorous premarket  
approval requirements, or can request a risk-based classification determination for  
the device in accordance with the “de novo” process, which is a route to market for

1 medical devices that are low to moderate risk, but are not substantially equivalent to  
2 a predicate device.

3 Registration Statement at 70-71.

4 35. The Registration Statement further described the Company's efforts to obtain  
5 regulatory approval for its exoskeleton product, the FDA's eventual approval of the product itself but  
6 not the classification of the product, and the postmarket regulatory environment to which the  
7 Company was subject.

8 36. While the Company acknowledged postmarket regulation in previous sections of its  
9 Registration Statement, it failed to make any mention of the FDA-required "postmarket surveillance"  
10 in the section titled "Postmarket Regulation." In fact, the phrase "postmarket regulation" is  
11 mentioned only three times in the entire Registration Statement.

12 37. Elsewhere in the Registration Statement, the Company disclosed the risks associated  
13 with government regulation, including an acknowledgement of the requirement of "postmarket  
14 surveillance," and the effect that the regulations and requirements could have on the success of  
15 ReWalk:

16 *We are subject to extensive governmental regulations relating to the*  
17 *manufacturing, labeling and marketing of our products.*

18 Our medical products and manufacturing operations are subject to regulation by the  
19 FDA, the European Union, the Ministry of Health in Israel, and other governmental  
20 authorities both inside and outside of the United States. These agencies enforce laws  
21 and regulations that govern the development, testing, manufacturing, labeling,  
22 storage, installation, servicing, advertising, promoting, marketing, distribution,  
23 import, export and market surveillance of ReWalk.

24 Our products are regulated as medical devices in the United States under the Federal  
25 Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the  
26 FDA. Under the FDCA, medical devices are classified into one of three classes—  
27 Class I, Class II or Class III—depending on the degree of risk associated with the  
28 medical device and the extent of control needed to provide reasonable assurance of  
safety and effectiveness. Classification of a device is important because the class to  
which a device is assigned determines, among other things, the necessity and type of  
FDA review required prior to marketing the device. See "Business—Government  
Regulation."

In June 2014, the FDA granted our petition for "*de novo*" classification, which is a  
route to market for medical devices that are low to moderate risk, but are not

1 substantially equivalent to a predicate device, and classified ReWalk as Class II  
 2 subject to certain special controls. The special controls established in the *de*  
 3 *novi* order include compliance with medical device consensus standards;  
 4 performance of a postmarket surveillance clinical study demonstrating a reasonable  
 5 assurance of safety and effectiveness in urban terrain; non-clinical performance  
 6 testing of the system's function and durability; a training program; and labeling  
 7 related to device use and user training. In order for us to market ReWalk, we must  
 8 comply with both general controls, including controls related to quality, facility  
 9 registration, reporting of adverse events and labeling, and the special controls  
 10 established for the device. Failure to comply with the general and special controls  
 11 could lead to removal of ReWalk from the market, which would have a material  
 12 adverse effect on our business.

13 Registration Statement 22-23.

14 38. The Registration Statement, including the above quoted excerpts, was false and  
 15 misleading because it failed to disclose material facts necessary to make the statements made not  
 16 misleading, as discussed below.

### 17 THE TRUTH IS REVEALED

18 39. The Registration Statement was false and misleading because it failed to disclose that  
 19 the Company was unprepared and/or unable to comply with the applicable "special controls"  
 20 requirement and provide the FDA with a postmarket surveillance study of the ReWalk product.

21 40. This crucial fact was omitted from its Registration Statement. In a Warning Letter  
 22 from the FDA to ReWalk, dated September 30, 2015, the FDA outlined ReWalk's substantial  
 23 failures to propose and commence an adequate postmarket surveillance plan.

24 41. Evidence of the Company's unpreparedness and/or inability at the time of the IPO to  
 25 comply with FDA regulations and, more specifically, provide the FDA with an adequate postmarket  
 26 surveillance ("PS") plan, is substantial. When the FDA's September 30, 2015, Warning Letter  
 27 became public, ReWalk's stock price dropped, as discussed below.

28 42. On June 24, 2014, the same day that the FDA authorized the marketing of the  
 ReWalk device, the FDA also ordered the Company to conduct postmarket surveillance in  
 accordance with section 522 of the Federal Food, Drug and Cosmetic Act (the "FFDCA"), 21 U.S.C.  
 § 3601, and Title 21 of the Code of Federal Regulations Part 822. The FDA issued this order (the  
 "522 Order") because the device's failure to prevent a fall was reasonably likely to cause serious

1 user injury and/or death to the user, as well as create a risk of harm to the individual assisting the  
2 user. The Company provided the FDA with a PS study plan synopsis in late July 2014.

3 43. By letter dated September 29, 2014, the FDA informed the Company that the  
4 Company's PS submission lacked the information needed to complete the review. The FDA listed  
5 the deficiencies in the Company's submission and required a complete response within 30 days.  
6 ReWalk did not timely respond.

7 44. By letter dated November 5, 2014, the FDA informed ReWalk that its response was  
8 overdue. The FDA then received a letter from the Company, dated November 6, 2014, enclosing a  
9 PS study plan. The FDA reviewed the plan and in a letter to the Company, dated February 13, 2015,  
10 informed the Company that the November 5, 2014, submission also lacked the information needed to  
11 complete the review. The FDA listed the deficiencies in the Company's second submission and  
12 required a complete response within 30 days. Again, ReWalk did not timely respond.

13 45. By letter dated March 16, 2015, the FDA informed the Company that a response to  
14 the FDA's February 13, 2015, letter was overdue. On March 20, 2015, the Company responded by  
15 email to the FDA and stated that a response would be submitted by April 15, 2015. The FDA did not  
16 receive that response by April 15, 2015.

17 46. By letter dated April 16, 2015, the FDA informed ReWalk that it sought a status  
18 update regarding its response to the FDA's February 13, 2015 letter. On May 22, 2015, the  
19 Company replied stating that it was in a position to respond on all but one issue and asked to discuss  
20 that issue with the FDA staff before submitting the formal response. The FDA attempted multiple  
21 times (by phone and email), from June 12, 2015 to July 28, 2015, to coordinate the requested  
22 teleconference with ReWalk to attempt to resolve these issues. The FDA also notified the Company  
23 in an email, dated June 24, 2015, that the FDA considered ReWalk's PS study to be out of  
24 compliance.

25 47. On July 29, 2015, ReWalk emailed the FDA and stated that it would have proposed  
26 dates for the teleconference by the week of August 3, 2015. On August 10, 2015, however, the  
27 Company notified the FDA for the first time that it was proposing substantial changes to the  
28



1 methods and study plan and requested an in-person meeting should the FDA have any questions  
2 regarding these major proposed changes.

3 48. On September 2, 2015, after reviewing the proposals in the Company's August 10,  
4 2015, letter, the FDA provided ReWalk feedback and recommended that it submit a revised PS study  
5 plan addressing this feedback and the deficiencies identified in the FDA's February 13, 2015 letter  
6 as soon as possible. The Company did not timely respond.

7 49. On September 30, 2015, the FDA issued a "Warning Letter" to Argo Medical  
8 Technologies, Inc. (the former name of ReWalk) stating that the Company was not in compliance  
9 with FDA regulations. The letter recounted the above facts and concluded as follows:

10 To date, FDA has received no response to this communication from your firm,  
11 [ReWalk] has not submitted a revised study plan, and there has been a substantial  
12 lack of progress towards commencement of the 522 PS study required under the 522  
13 Order.

14 Further, as stated within the 522 Order, a manufacturer must commence surveillance  
15 under section 522 of the Act not later than 15 months after the day on which an order  
16 is issued under section 522 (see section 522(b) of the Act). The 15-month time frame  
17 within which [ReWalk's] PS study plan must be approved and its study must be  
18 commenced closed on September 28, 2015.

19 Failure or refusal of a manufacturer to comply with requirements under section 522  
20 of the Act, which includes requirements specified under 21 CFR Part 822, is a  
21 prohibited act under section 301(q)(1)(C) of the Act, 21 U.S.C. §  
22 331(q)(1)(C). Further, failure or refusal to comply with a requirement under section  
23 522 of the Act renders a device misbranded under section 502(t)(3) of the Act, 21  
24 U.S.C. § 352(t)(3).

25 [ReWalk Robotics Ltd.] has:

- 26 • failed to submit a revised PS study plan that adequately addresses the deficiencies  
27 described in FDA's September 29, 2014 letter, as well as those deficiencies described  
28 in FDA's February 13, 2015 letter (see 21 CFR 822.19);
- failed to design a PS study plan that answers the questions identified in the 522 Order  
(see 21 CFR 822.11);
- failed to have an approved PS study plan (see 21 CFR 822.20); and
- failed to commence surveillance under section 522 of the Act not later than 15  
months after the day on which the 522 Order was issued (see section 522(b) of the  
Act).

1 Therefore, [ReWalk] has committed a prohibited act under section 301(q)(1)(C) of  
 2 the Act by failing to comply with requirements under section 522 of the Act. Your  
 3 firm's ReWalk device, authorized for marketing under de novo classification  
 (K131798/DEN130034), is currently misbranded under section 502(t)(3) of the Act.

4 You should take prompt action to correct these violations. Failure to promptly correct  
 5 these violations may result in regulatory action being initiated by FDA without  
 6 further notice. These actions include, but are not limited to, seizure, injunction,  
 7 and/or civil money penalties. Please note that Federal agencies are advised of the  
 issuance of all Warning Letters about devices so that they may take this information  
 into account when considering the award of contracts.

8 Within fifteen (15) calendar days from the date you receive this letter, please submit  
 9 your firm's section 522 post-market surveillance study plan that addresses the  
 10 deficiencies identified in the FDA letters dated September 29, 2014 and February 13,  
 11 2015. In addition, please notify this office in writing of the specific steps you have  
 12 taken to correct the noted violations, as well as those actions performed to prevent  
 13 recurrence for this order and future studies. Include documentation of the corrective  
 actions you have taken. If your planned corrections will occur over time, please  
 include a timetable for implementation of those corrections. If corrective actions  
 cannot be completed within 15 calendar days, state the reason for the delay and the  
 time within which the corrections will be completed.

14 50. On May 10, 2016, the Company revealed that, at the time of the IPO, it had been  
 15 unprepared and/or unable to timely and adequately comply with the FDA's "special controls" due to  
 16 inadequate staffing. According to the Company's 10-Q, filed with the SEC on May 10, 2016:

17 *The FDA has sent us letters suggesting a potential need for us to seek new pre-*  
 18 *market clearance for our ReWalk Personal 6.0 and stating that it may take*  
 19 *regulatory action for deficiencies in our mandatory post-market surveillance study*  
*on the device.*

20 On September 30, 2015, we received a warning letter (the "September 2015 Letter")  
 21 from the Food and Drug Administration (the "FDA") citing deficiencies in our  
 22 protocol for a post-market surveillance study of our ReWalk Personal and our failure  
 23 to initiate a post-market study by the September 28, 2015 deadline. Between June  
 24 2014 and our receipt of the September 2015 Letter, we submitted our post-market  
 25 study protocol to the FDA, amended the protocol in response to the FDA's  
 26 subsequent request and proposed additional amendments to enhance the protocol  
 27 after the FDA notified us that our subsequently-amended protocol was still deficient.  
 28 While we responded to the FDA's requests throughout this period, we did not submit  
 all of our responses on a timely basis. The September 2015 Letter warned that the  
 FDA could take regulatory action against us for violations of Section 522 of the  
 Federal Food, Drug and Cosmetic Act ("Section 522") based on the late post-market  
 study and allegedly deficient protocol for that study. In February 2016, the FDA sent  
 us an additional information request (the "February 2016 Letter") requesting  
 additional changes to our post-market surveillance study protocol and asking that we



1 comply within 30 days. In the February 2016 Letter, the FDA also expressed its  
2 belief that we should submit a new pre-market notification for our ReWalk device  
stemming from the FDA's review of what it considered to be changes to the device.

3 We held several discussions with the FDA, including an in-person meeting in March  
4 2016, which based on our understanding of the conclusions reached by the FDA,  
5 resulted in the FDA narrowing its request for a new pre-market notification to an  
6 abbreviated, special application (the "special 510(k)"). This special 510(k) relates  
7 only to a computer included with the ReWalk device and is subject to an approximate  
8 30-day review period, rather than the standard 90-day review period for pre-market  
9 applications. In late March 2016, the FDA confirmed that, based on these resolutions,  
10 we could continue to market our ReWalk device as long as we submit the special  
11 510(k) and initiate the post-market study by June 1, 2016. Our special 510(k)  
12 submission was received by the FDA on April 11, 2016, at which time the FDA  
13 commenced its review of the special 510(k). Additionally, we have submitted a  
14 protocol for the post-market surveillance study that was approved by the FDA on  
15 May 5, 2016 and that we are required to commence within 30 days after that date.  
We expect to initiate our post-market surveillance study by the end of May 2016.  
The FDA also confirmed that, based on the public health significance of the ReWalk  
device, it did not view regulatory action against us for the late start in or deficient  
protocol for the post-market study as a priority for the agency, and that it expected to  
reassess the issues surrounding the pre-market notification and post-market study in  
June 2016. We have met all deadlines for submission of responses and have  
communicated regularly with the FDA after receiving each of the September 2015  
Letter and the February 2016 Letter.

16 We expect we will be able to adhere fully to the FDA's timeline and to respond  
17 promptly to the FDA's requests based on significant additions in staffing aimed at  
18 addressing a need for greater internal clinical and regulatory resources. However, if  
19 we are unable to satisfy this timing or if the results of our post-market clinical study  
20 are not as favorable as we expect, the FDA may issue additional warning letters to  
21 us, may impose limitations on the labelling of our device or may limit us to  
22 marketing a previous version of the ReWalk device in the United States. We derived  
65% of our revenues in 2015 from sales of the ReWalk device in the United States  
and, if we are required to market a previous version of the ReWalk device in the  
United States, we expect that these sales would be adversely impacted, which could  
materially adversely affect our business and overall results of operations.

23 March 31, 2016 Form 10-Q, filed May 10, 2016, at 28. The Company thus belatedly admitted that it  
24 was previously unprepared and is only now able to attempt to comply with the FDA's "special  
25 controls" due to "significant additions in staffing aimed at . . . internal clinical and regulatory  
26 resources."

27 51. At the time of its IPO, ReWalk was: (i) unprepared and/or unable to comply with the  
28 522 Order (21 U.S.C. § 3601); (ii) unprepared and/or unable to provide the FDA with adequate

1 details concerning its postmarket surveillance study; and (iii) unprepared and/or unable to undertake  
2 an adequate postmarket surveillance study.

3 52. Compliance with the FDA's "special controls" was critical to the Company's ability  
4 to continue to market and sell its product. As such, the facts regarding the Company's ability to  
5 comply with those "special controls," should have been disclosed. ReWalk's failure to do so was a  
6 material omission which rendered the Registration Statement false and misleading.

7 53. At a minimum, ReWalk should have disclosed in the Registration Statement that its  
8 own internal clinical and regulatory resources were then insufficient to enable the Company to  
9 comply with the FDA's postmarket surveillance requirements. The Registration Statement should  
10 have disclosed that to cure this deficiency, it was incumbent on the Company to hire or contract for a  
11 larger number of skilled employees to enable ReWalk to plan, undertake, and timely complete an  
12 adequate postmarket surveillance study that would satisfy FDA standards. The Registration  
13 Statement, however, disclosed no such facts or deficiencies, nor did it contain any information  
14 explaining to investors that ReWalk then needed "significant additions in staffing" to carry out a  
15 postmarket surveillance study. This was a material omission that went to the heart of ReWalk's  
16 business.

17 54. Moreover, ReWalk's repeatedly failed to satisfy the FDA for more than a year after  
18 the IPO, which hurt ReWalk's ability to increase its revenues. ReWalk's delay in FDA compliance  
19 also impeded ReWalk's ability to persuade third-party payors, like Medicare and private pay  
20 insurers, that the ReWalk Personal model improved patient health and strength, and thus merited  
21 insurance coverage or reimbursement.

22 55. The Company's failure to comply with Section 522 of the FFDCA, 21 U.S.C. § 3601,  
23 and undertake the necessary steps in connection with its postmarket surveillance obligations,  
24 compromised its ability to ensure that third parties would pay or provide reimbursements for the  
25 ReWalk products. The information necessary to allow insurers to determine whether to pay for new  
26 medical devices is often available only after the device has been in use. Postmarket surveillance data  
27 assists in this determination. The absence of such data jeopardizes insurance coverage. This  
28 presented additional risk that ReWalk failed to disclose.

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- a. whether defendants violated the 1933 Act;
- b. whether statements made by defendants to the investing public in the Registration Statement and Prospectus for the IPO misrepresented material facts about the business and prospects of ReWalk; and
- c. to what extent the members of the Class have sustained damages and the proper measure of damages.

## NO SAFE HARBOR

64. First, Section 27(A) of the Securities Act of 1933 provides that the statutory safe harbor “shall not apply to a forward-looking statement that is made in connection with an initial public offering.” 15 U.S.C. § 77z-2(b)(2)(D).

66. Third, to the extent that any statements may be construed as forward-looking, those statements were not accompanied by meaningful cautionary language identifying important facts that could cause actual results to differ materially from those in the statements.

**FIRST CAUSE OF ACTION**

**For Violations of Section 11 of the 1933 Act  
Against All Defendants**

67. Plaintiff incorporates ¶¶ 1 -66 by reference.

68. This Cause of Action is brought pursuant to §11 of the 1933 Act, 15 U.S.C. §77k, on behalf of the Class, against all defendants.

69. The Registration Statement for the IPO was inaccurate and misleading, contained untrue statements of material facts, omitted to state other facts necessary to make the statements made not misleading, and omitted to state material facts required to be stated therein.

70. ReWalk is the registrant for the IPO. The defendants named herein were responsible for the contents and dissemination of the Registration Statement.

71. As issuer of the shares, ReWalk is strictly liable to Plaintiff and the Class for the misstatements and omissions.

72. None of the defendants named herein made a reasonable investigation or possessed reasonable grounds for the belief that the statements contained in the Registration Statement were true and without omissions of any material facts and were not misleading.

73. By reason of the conduct herein alleged, each defendant violated, and/or controlled a person who violated §11 of the 1933 Act.

74. Plaintiff acquired ReWalk common stock pursuant and/or traceable to the Registration Statement for the IPO.

75. Plaintiff and the Class have sustained damages. The value of ReWalk common stock has declined substantially subsequent to and due to defendants' violations.

76. At the time of his purchase of ReWalk common stock, Plaintiff and other members of the Class were without knowledge of the facts concerning the wrongful conduct alleged herein and could not have reasonably discovered those facts prior to February 25, 2016. Less than one year has elapsed from the time that plaintiff discovered or reasonably could have discovered the facts upon which this complaint is based to the time that plaintiff filed this complaint. Less than three years has

1 elapsed between the time that the securities upon which this Cause of Action is brought were offered  
2 to the public and the time Plaintiff filed this complaint.

### 3 SECOND CAUSE OF ACTION

#### 4 **For Violation of Section 12(a)(2) of the 1933 Act** 5 **Against All Defendants**

6 77. Plaintiff incorporates ¶¶1 -67 by reference.

7 78. This claim is asserted against Defendants ReWalk, the Individual Defendants, and the  
8 Underwriter Defendants. This claim does not sound in fraud. For purposes of this Section 12(a)(2)  
9 claim, Plaintiff does not allege that any Defendant acted with scienter or fraudulent intent, which are  
10 not elements of a claim under Section 12(a)(2) of the Securities Act of 1933. This claim is based  
11 solely on negligence. Plaintiff specifically disclaims any allegation of fraud, scienter or recklessness  
12 in this Section 12(a)(2) claim.

13 79. By means of the defective Prospectus, defendants ReWalk, the Individual Defendants  
14 and the Underwriter Defendants promoted and sold ReWalk stock to Plaintiff and other members of  
15 the Class.

16 80. The Prospectus contained untrue statements of material fact, and/ or concealed or  
17 failed to disclose material facts, as detailed above. The defendants named in this Cause of Action  
18 owed Plaintiff and the other members of the Class who purchased ReWalk common stock pursuant  
19 to the Prospectus the duty to make a reasonable and diligent investigation of the statements  
20 contained in the Prospectus to ensure that such statements were true and that there was no omission  
21 to state a material fact required to be stated in order to make the statements contained therein not  
22 misleading. These defendants, in the exercise of reasonable care, should have known of the  
23 misstatements and omissions contained in the Prospectus as set forth above.

24 81. Plaintiff did not know, nor in the exercise of reasonable diligence could have known,  
25 of the untruths and omissions contained in the Prospectus at the time Plaintiff acquired ReWalk  
26 common stock.

27 82. By reason of the conduct alleged herein, Defendants violated section 12(a)(2) of the  
28 1933 Act. As a direct and proximate result of such violations, Plaintiff and the other members of the

1 Class who purchased ReWalk common stock pursuant to the Prospectus sustained substantial  
2 damages in connection with their purchases of the stock. Accordingly, Plaintiff and the other  
3 members of the Class who hold the common stock issued pursuant to the Prospectus have the right  
4 to rescind and recover the consideration paid for their shares, and hereby tender their common stock  
5 to the defendants sued herein.

6 83. Class members who have sold their common stock seek damages to the extent  
7 permitted by law.

8 **THIRD CAUSE OF ACTION**

9 **For Violation of Section 15 of 1933 Act**  
10 **Against the Individual Defendants**

11 84. Plaintiff incorporates ¶¶1 -67 by reference.

12 85. This Cause of Action is brought pursuant to §15 of the 1933 Act against ReWalk and  
13 the Individual Defendants.

14 86. The Individual Defendants each were control persons of ReWalk by virtue of their  
15 positions as directors and/or senior officers of ReWalk. The Individual Defendants each had a series  
16 of direct and/or indirect business and/or personal relationships with other directors and/or officers  
17 and/or major shareholders of ReWalk. The Company controlled the Individual Defendants and all of  
18 ReWalk's employees.

19 87. The defendants each were culpable participants in the violations of §11 of the 1933  
20 Act alleged in the Cause of Action above, based on their having signed or authorized the signing of  
21 the Registration Statements and having otherwise participated in the process which allowed the IPO  
22 to be successfully completed.

23 **PRAYER FOR RELIEF**

24 WHEREFORE, Plaintiff prays for relief and judgment, as follows:  
25  
26  
27  
28



Plaintiff hereby demands a trial by jury.

**GLANCY PRONGAY & MURRAY LLP**

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